APR 2 6 2002

K020690

Ocu-Ease
Optical Products, Inc.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Assigned 510(k) Number: **K020690**

Applicant Information:

Date Prepared:	April 16, 2002
Name: Address:	Ocu-Ease Optical Products, Inc. 629 Tennent Avenue Pinole, CA. 94564
Contact Person:	Charles R. Vermette, President
Phone/Fax Number:	Phone: (510)724-0384 Fax: (510)724-4842

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Device Trade Name:	Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens

Equivalent Devices:

The Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens is substantially equivalent to the predicate devices identified below in terms of intended use and design.

Predicate Device: (substantially equivalent to indication use)

1. Custom Prosthetic Soft Lens (hefilcon A)
   Manufactured by Prosthetic Soft Lens Corp.
   Englewood, CO.
   510(k) #K992950

2. Ocu-Flex-53 (ocufilcon B) Soft Contact Lens
   Ocu-Ease Optical Prod.
   Pinole, CA.
   PMA#P820051

Device Description:

The dimensions of the Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens are the same as approved in PMA #P820051.

The physical properties of the lens are:

Refractive Index	1.41
Light Transmission	varies depending on prosthetic design
Specific Gravity	1.18
Water Content	53%
Color Pigment Name	Titanium dioxide
Oxygen Permeability	18.1×10^{-11} @ 35°C (Revised Fatt Method)

The lens material (ocufilcon B) is a hydrophilic copolymer of 2-hydroxyethyl methacrylate, methacrylic acid and cross-linked with ethylene glycol dimethacrylate, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution. The Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft (hydrophilic) Contact Lens is a partially or totally white opaque lens that can be painted or printed with an iris or other pattern to mask a disfiguring or unsightly eye condition. The lens may be totally opaque for a non-sighted eye or clear in the center for a sighted eye.

The approved pigment, titanium dioxide, is incorporated into the monomer during polymerization with the help of a coupling agent. The titanium dioxide is evenly distributed throughout the lens and cannot be extracted.

The Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft (hydrophilic) Contact Lens is available to the practitioner in the following opaque patterns:

- **Clear Lens with Opaque Pupil**: pupil sizes available in 2.0mm to 17.5mm.
- **Solid Opaque Lens**: a solid opaque (white lens). Available to full lens diameter.
- **Solid Opaque with Clear Pupil**: opaque diameter range 2.0mm to full lens diameter. Clear pupil diameter range 2.0mm to 8.0mm
- **Solid Annular Opaque with Clear Pupil & Clear Edge**: clear pupil sizes available in 2.0mm to 8.0mm. Annular opacity available to 15.5mm

Statement of Intended Use:

The Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lenses are indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for cosmetic management of conditions such as corneal, iris or lens abnormalities; or for persons wishing to change the appearance of their eyes without eye abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia or astigmatism) in aphakic or not-aphakic persons or for occlusive therapy conditions such as diplopia, amblyopia or extreme photophobia.

The lens may be disinfected using a chemical (not heat) disinfection system only.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Ocu-Ease Optical Products, Inc. The established safety profile (preclinical toxicology and manufacturing/chemistry data) of the device is equivalent to the Ocu-Flex 53 (ocufilcon B) Soft (Hydrophilic) Contact Lens for daily wear PMA P820051, and the Prosthetic (hefilcon A) Soft Lens, 510(k) K992950. Being similar with respect to materials, physical construction and safety and effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above.

Substantial Equivalence Matrix

	Characteristic	Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens Soft Contact Lenses		***Predicate Device:*** Ocu-Flex-53 (ocufilcon B) Soft Contact Lens
1.)	**PRODUCTION METHOD**	Lathe-cut		Lathe-cut
2.)	**INTENDED USE**	Daily Wear, Soft (hydrophilic) contact lens		Daily Wear, Soft (hydrophilic) contact lens
3.)	**INDICATION**	To enhance and/or alter the apparent eye color. The lens may also be prescribed for the correction of refractive ametropia (myopia hyperopia or astigmatism) or for occlusive therapy conditions such as diplopia, amblyopia or extreme photophobia.		Correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia, hyperopia and astigmatism
4.)	**FDA "LISTED" COLOR ADDITIVES**	Titanium dioxide		Reactive blue 19, reactive blue 21 and Reactive yellow 15
5.)	**USES AND RESTRICTIONS**	The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.		The color additives listed above may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.
6.)	**Colors Offered**	Opaque		Azure, Baby-blue, Turquoise

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2002

Ocu-Ease Optical Product, Inc.
Charles R. Vermette, President
629 Tennent Avenue
Pinole, CA 94564

Re: K020690
Trade/Device Name: Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: February 25, 2002
Received: March 4, 2002

Dear Mr. Vermette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **Ocu-Flex-53 Custom Prosthetic (ocufilcon B) Soft Contact Lens**

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The lens may be disinfected with a chemical (not heat) disinfection system.

Daniel W. Brown PH.D

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020690

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Division of Ophthalmic Devices

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)